

**MEDTRONIC Sofamor Danek
PEEK PREVAIL® Cervical Interbody Device
November 9, 2011**

- I. **Company:** Medtronic Sofamor Danek, Inc.
 1800 Pyramid Place
 Memphis, Tennessee 38132
 (901) 396-3133
- II. **Contact:** Kristi Frisch
 Regulatory Affairs Specialist
- III. **Product Name:** PEEK PREVAIL® Cervical Interbody Device
- IV. **Common Name:** Intervertebral Fusion Device
- V. **Classification:** 21 CFR 888.3080 – Product Code: OVE
- VI. **Predicate:** PEEK PREVAIL® Cervical Interbody Device
 (K094042)
- VII. **Description:** The PEEK PREVAIL® Cervical Interbody Device is an intervertebral body fusion device with internal screw fixation. The screws protrude through the interbody portion of the device and stabilize the vertebral body while preventing expulsion of the implant. The implant is “I-Beam” shaped with a 2 screw midline configuration. This device is intended to be radiolucent and the interior space of the product is to be used with autograft.
- The PEEK PREVAIL® Cervical Interbody device implant is manufactured from PEEK Optima LT1® and contains tantalum radiopaque markers and a Nitinol screw locking mechanism. The screws used with this device (ZEPHIR® Anterior Cervical Screws) are manufactured from Titanium Alloy.
- VIII. **Indications for Use:** The PEEK PREVAIL® Cervical Interbody Device is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The PEEK

PREVAIL® Cervical Interbody Device must be used with internal screw fixation provided by ZEPHIR® Anterior Cervical Screws. The PEEK PREVAIL® Cervical Interbody Device implants are to be used with autograft and implanted via an open, anterior approach. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

- IX. **Technological Characteristics:** The purpose of this 510(k) is to include an additional instrument in the system to allow surgeons a tool to guide the screw into the interbody device and bone at the appropriate trajectory. Associated labeling changes were made based on the addition of the new instrumentation.
- X. **Substantial Equivalence:** Documentation was provided which demonstrated the subject intervertebral devices to be substantially equivalent to PEEK PREVAIL® Cervical Interbody Device components previously cleared in K094042 (S.E. 06/30/2010).
- XI. **Non-Clinical Testing:** The subject and predicate PEEK PREVAIL® Cervical Interbody Device are identical in terms of indications for use, intended use, performance specifications, and technological characteristics. Cleaning and sterilization assessments have been performed to provide the appropriate instructions for the use of the PEEK PREVAIL device.
- XII. **Conclusions Drawn from the Non-Clinical Tests:** The information above demonstrates equivalence and supports a determination of substantial equivalence between the subject and predicate PEEK PREVAIL® Cervical Interbody Device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Medtronic Sofamor Danek, Inc.
% Ms. Kristi Frisch
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

JAN 17 2012

Re: K113252
Trade/Device Name: PEEK PREVAIL® Cervical Interbody Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: November 1, 2011
Received: November 3, 2011

Dear Ms. Frisch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

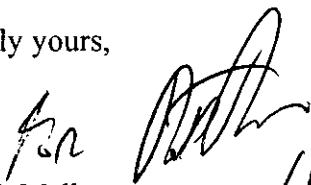
Page 2 – Ms. Kristi Frisch

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K113252

Device Name: PEEK PREVAIL® Cervical Interbody Device


Indications for Use:

The PEEK PREVAIL® Cervical Interbody Device is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The PEEK PREVAIL® Cervical Interbody Device must be used with internal screw fixation provided by ZEPHIR® Anterior Cervical Screws. The PEEK PREVAIL® Cervical Interbody Device implants are to be used with autograft and implanted via an open, anterior approach. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

Prescription Use x OR Over-The-Counter Use _____
Per 21 CFR 801.109

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113252